REMARKS

The Applicants acknowledge the Examiner's comprehensive Office Action, **a Final Rejection**, with appreciation. Claims 26-44 remain pending in the application; however, Claims 33-44 remain withdrawn from consideration as a result of the previously issued Restriction Requirement. The Office maintains a prior art rejection under 35 USC § 103.

Claims 26-32 remain rejected for obviousness under 35 USC § 103(a) based on the disclosure of Watts, et al. (International Publication No. WO 02/34259). The Office reiterates its analysis of the Watts, et al. disclosure, stating that Watts, et al. disclose a composition comprising a peroxisome proliferator activated receptor (PPAR) activator and a benzoquinone. With respect to the disclosed PPAR activators, the Office states that Watts, et al. disclose that a number of PPAR activators are known in the art, including the fibrate and thiazolinedione classes of drugs. With respect to the disclosed benzoquinones, the Office states that Watts, et al. disclose that such compounds have antioxidant properties and that the preferred benzoquinone is ubiquinone or coenzyme Q_{10}.

It remains the position of the Office that based on the disclosure of Watts, et al., it would have been obvious to one skilled in the art to use bezafibrate or a combination of rosiglitazone and fenofibrate in combination with an antioxidant such as coenzyme Q_{10} to arrive at the instantly claimed compositions. It is the further position of the Office that one skilled in the art would have been motivated to formulate such a composition since a composition comprising a PPAR ligand in combination with an antioxidant has been previously taught in the art to be useful for lowering triglycerides. Thus, the Office concludes that, based on this known activity, one skilled in the art would have had a reasonable expectation of success that compositions comprising a PPAR ligand and an antioxidant would be effective for treating conditions such as obesity and atherosclerosis.

With respect to the pharmacological data presented in the DACQUET Declaration submitted with the Response and Amendment of January 9, 2009, it is the position of the Office that the nature of the control used in the studies is not clear and that the absence of control data makes it unclear as to the actual combination which gave the unexpected results. It is the further position of the Office that treatment with coenzyme Q_{10} alone achieves better results than treatment with a combination comprising a PPARγ ligand and coenzyme Q_{10}. The Office also states that the data presented in the Declaration are not commensurate with the full scope of the claims. Moreover, it is the further position of the Office that the claimed compositions (i.e., a combination of a PPAR ligand and benzoquinone (an antioxidant)) are taught by the disclosure of Watts, et al., and that properties such as those demonstrated in the Declaration would be inherent in the compositions disclosed in the cited reference.

The Applicants respectfully submit that weight gain is an art-recognized deleterious side effect associated with administration of PPAR ligands. The Applicants further submit that, contrary to the Office allegation, administration of coenzyme Q_{10} alone does not produce weight gain reduction. The data disclosed in the previously submitted DACQUET Declaration demonstrate that administration of coenzyme Q_{10} alone produces no weight gain reduction (i.e., coenzyme Q_{10} performs the same as control). Moreover, as noted in the Response and Amendment of January 9, 2009, the data disclosed at pages 7-8 of the specification demonstrate that rosiglitazone causes weight gain in obese mice and that treatment with a combination of rosiglitazone and coenzyme Q_{10} reverses this weight gain.

With the instant Amendment, the claims have been amended to recite a composition comprising rosiglitazone and coenzyme Q_{10}. Support for this amendment may be found at page 7 of the specification and in previous Claim 31, which has been cancelled with the present Amendment. The Applicants respectfully submit that no new matter has been introduced by this Amendment.

The Applicants also provide a second Declaration by Dr. Catherine DACQUET which further demonstrates the superior and unexpected effects associated with the instantly claimed compositions. Specifically, the Declarant provides data which

demonstrate that a combination of rosiglitazone and coenzyme Q_{10} reduces insulinemia in mice and that the effects exhibited by the combination are greater than the effects observed with rosiglitazone alone. As noted above, the data disclosed at pages 7-8 of the specification demonstrate that rosiglitazone alone causes weight gain in obese mice and that treatment with a combination of rosiglitazone and coenzyme Q_{10} reverses this weight gain. The Declarant also provides additional data which demonstrate that a combination of rosiglitazone and coenzyme Q_{10} significantly reduces the weight of epididymal visceral fat in obese mice whereas administration of rosiglitazone alone increases the weight of epididymal visceral fat in obese mice (as discussed above, administration of coenzyme Q_{10} alone has no effect on weight reduction).

The Declarant also provides data for the species combination disclosed in the Watts, et al. reference (i.e., fenofibrate and coenzyme Q_{10}). These data demonstrate that a combination of fenofibrate and coenzyme Q_{10} is significantly less effective in reducing insulinemia than a combination of rosiglitazone and coenzyme Q_{10}. Moreover, the combination of fenofibrate and coenzyme Q_{10} does not reduce the weight of epididymal visceral fat in obese mice. Thus, the synergy observed with the combination comprising rosiglitazone and coenzyme Q_{10} is not observed with the combination comprising fenofibrate and coenzyme Q_{10}.

The Applicants respectfully submit that the surprising and unexpected effects associated with the instantly claimed combination would not have been predicted based on the prior art of record in the instant application. Such demonstration is directly responsive to the Office enquiry. Reconsideration and withdrawal of the obviousness rejections under 35 USC § 103(a) is respectfully requested.

Finally, in accordance with MPEP § 821.04, the Applicants request rejoinder of withdrawn method Claims 33-44 upon the identification of allowable subject matter.

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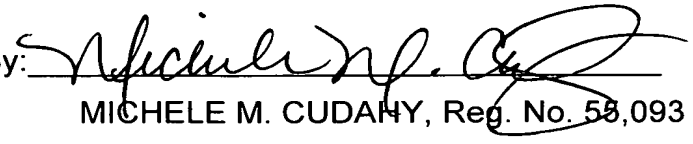
Accordingly, entry of the present amendment and the present DACQUET Declaration into the record of the application, rejoinder of the withdrawn method claims, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned agent has made an earnest effort to place this application into condition for immediate allowance. If she can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call her at her below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

By: 

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Enclosure: Request for Continued Examination (RCE) under 37 CFR § 1.114; Check No. 77378 (in the amount of $810.00) for RCE Fee; Check No. 77379 (in the amount of $1,110.00) for Three (3) Month Extension Fee; DACQUET Declaration; Listing of Claims; and Postal Card Receipt

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THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.